

# **EXHIBIT 500.1**

PLAINTIFFS' EXHIBITS 000764

**David M. Bliesner, Ph.D.**

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**GOAL:**

To use my regulatory, quality assurance, leadership, project management and technical skills to help organizations improve their level of compliance with the Current Good Manufacturing Practices (CGMPs), Current Good Laboratory Practices (CGLPs) and Quality System Regulations (QSRs).

**EXPERIENCE:**

**2/99 - Present**

**Delphi Analytical Services Inc., Indian Rocks Beach, Florida**  
President

Founded and run Delphi Analytical Services, Inc. Delphi Analytical Services, Inc. ([www.delphianalytical.com](http://www.delphianalytical.com) and [www.delphianalytical.biz](http://www.delphianalytical.biz)) (Delphi) provides collaborative-consulting, to the pharmaceutical, biopharmaceutical, medical device, and contract analytical laboratory industries. This primarily takes the form of client site visits working one-on-one to meet individual needs. In addition, Delphi offers prepared lectures, courses, and e-learning relating to technical aspects of the laboratory control and other CGMP quality systems. We also provide assistance in establishing appropriate quality systems, and functions to help maximize compliance with FDA regulations and make effective use of all available resources. Delphi is capable and prepared to help customers start new businesses and business units within their organizations. Over the last several years Delphi has been actively involved as part of the "expert consultant" contingent for two large pharmaceutical companies under consent decree with the FDA. During these assignments we have honed our expertise in auditing GMP facilities, and developing, implementing, and verifying corrective action plans under FDA timelines. Delphi has also developed the V-SOP© System and V-Training© Approach, a patent pending video-based document creation, process improvement and training technology. Dr. Bliesner is also sole author of "Establishing a CGMP Laboratory Audit System: A Practical Guide" and "Validating Chromatographic Methods: A Practical Guide" both published by John Wiley & Sons, Inc. Hoboken, New Jersey.

**3/01-6/02**

**Laboratory Management Systems, Inc. New Castle, Delaware**  
Vice President, Operations

Served as a contract Vice President, Operations for Laboratory Management Systems, Inc. LMSi (now Thermo-Fischer) is a consulting, and instrument services business specifically focused on providing services to FDA regulated laboratories. Authored LMSi's three-year business plan, which was used to sell the company to the Thermo Electron Corporation for over \$10 million. Created and drove focused sales & marketing plans. Set specific financial growth goals. Brought in the new business necessary to meet LMSi financial goals. Maintained and coordinated influx of personnel to support new business. Assisted in managing cash flow of the company. Coordinated with the corporation officers regarding the above functions. Assured adherence to the LMSi business plan. Served as a member of the Executive Committee. Functioned as consultant and trainer in the field of FDA compliance to GMPs and GLPs. Served as company president in the absence of the founder. LMSi was an INC Magazine top 500 Company in the year 2000, 2002 and 2003.

**12/97 - 2/99**

**Restek Corporation, State College, Pennsylvania**  
Director, Restek Analytical Services

Responsible for the conception, design, building, staffing, and qualification of Restek Analytical Services (RAS). This included conducting market research, drafting a business plan, and obtaining funding and approval from Restek upper management amounting to over \$875,000. RAS, a division of Restek Corporation, is a unique, innovative chromatography laboratory designed to deliver both quality services and quality products. These products and services are tailored to meet the needs of the pharmaceutical industry. RAS is a CGMP chromatography laboratory. It offers analytical method development and validation, HPLC/GC education and training, custom stationary phase design, and CGMP/regulatory services and support. In addition, RAS is actively involved in fundamental chromatographic research and presentation of those discoveries. Had overall profit/loss responsibility for RAS. 1999 operating budget was approximately \$1.37 million and capital budget was \$164,000.

**7/97 - 12/97**

**Restek Corporation, State College, Pennsylvania**  
HPLC Product Marketing Manager

Responsible for entire HPLC product line. This included designing and implementing marketing plans and generating revenue projections. Worked with graphics department to generate new HPLC catalog and additional technical literature and presentations. Also responsible for traveling with the Restek technical sales representatives to customer sites and trade shows. Customer education and training were an important part of these responsibilities. Hired R&D chemist and developed an extensive plan for developing new and unique HPLC phases. Efforts as HPLC Product Marketing Manager increased revenues from \$176,000 in 1997 to \$412,000 in 1998. Final sales for 1999 exceeded \$650,000.

**7/95 - 5/97**

**Somerset Pharmaceuticals, Inc., Tampa, Florida**

Director of Analytical Research and Development/Quality Control

Senior Analytical Laboratory supervisor at Somerset. Extensive experience in personnel recruitment, supervision and evaluation. Responsible for establishment and overall operation of analytical laboratory, including personnel training, implementation of CGMPs, and generation of analytical data for CMC section of NDAs and INDs. Actively involved in developing analytical methods and experimental protocols for investigating new chemical entities. Also, assisted in designing and executing stability protocols, and designing and implementing cleaning validation studies. Involved in new formulation development including excipient compatibility and stability studies. Represented Somerset's scientific interests in negotiations with potential bulk drug suppliers and numerous vendors. Have supervised, compiled data, and written CMC section for IND #51,924. Overall responsible for generation of methods and data found in NDA #20-647 CMC section.

**1/95 - 7/95**

**Somerset Pharmaceuticals, Inc., Tampa, Florida**

Analytical Laboratory Manager

Supervised day-to-day operation of analytical laboratory, and personnel, including methods validation, routine analysis, and equipment qualification/calibration. Supervised execution of stability and experimental protocols.

**6/94 - 1/95**

**UDL Laboratories, Inc., Largo, Florida**

Analytical Group Leader

Primarily responsible for supervising research chemists. Also, responsible for reviewing validation reports, GMP notebooks, and other raw data used in ANDA submissions. Designed and implemented GMP and analytical

skills training programs. Also, designed a secure data storage system.

**4/94 - 6/94**

**UDL Laboratories, Inc., Largo Florida**

Principal Chemist

Responsible for developing and validating analytical methods for the analysis of pharmaceuticals. Primary emphasis on HPLC method development and corresponding validation reports.

**8/92 - 4/94**

**Zeneca, Inc., Wilmington, Delaware**

Analytical Research Chemist

Responsible for developing and validating analytical methods for the analysis of pharmaceuticals. Involved in all stages of product development from exploratory to the regulatory phases. Experienced in HPLC, TLC, dissolution testing, and conducting primary solution stability studies. Worked closely with formulation specialists to design testing protocols and methods for new dosage forms. Actively involved in researching new technologies to include solid state NMR, charged coupled device data capture and processing for TLC, and the use of FTIR for in situ TLC analysis. Experienced in method and report writing. Received training and worked in a GMP environment. Chairman of both the Analytical Development Department and Pharmaceutical Research and Development Group committees established to deal with CGMP compliance issues in preparation for pre-approval inspections. Extensive experience in the use of PC and VAX-based software.

**8/88 - 8/92**

**University of Vermont, Burlington, Vermont**

Graduate Teaching Fellow

In charge of the chemistry majors' advanced integrated laboratory course. Taught GC, LC, AA, FTIR, FT-NMR, UV/VIS, and X-ray techniques in an integrated laboratory environment. Also provided instruction in handling of air sensitive compounds and proper scientific report writing. Responsible for the development and implementation of an FT-NMR experiment. Also, aided in supervising undergraduate research projects within my own research group. This involved instruction in NMR, use of chromatographic application software, and guidance in chromatographic system troubleshooting.

**5/83 - 8/88**

**Commissioned Officer, United States Marine Corps**

Camp Baret, Quantico, Virginia and Camp Butler, Okinawa, Japan

Served as a Unit Commander, Unit Executive Officer/Fire Direction Officer, Field Artillery Instructor, and Unit Liaison Officer. Primarily responsible for the leadership, training, welfare, and morale of a 65 - man artillery unit including extensive family interaction and support. Additional responsibilities included annual budget planning exceeding \$300,000 a year. Also, responsible for the maintenance of an equipment account in excess of \$2 million and field and classroom instruction of all new Marine Lieutenants on the proper application of artillery fires. While stationed in Okinawa, Japan, duties included extensive planning and coordination of field operations to include combat loading of over 50 major pieces of equipment and 200 personnel onto Naval ships and Air Force aircraft. These actions required extensive coordination and interaction with U.S. Navy, U.S. Air Force, Korean Marine Corps, Philippine Civil Servants, and Marine Corps higher headquarters.

**SPECIALITIES:** Quality Assurance Auditing and Oversight, Small and Large Unit Leadership, Project Management, Process Mapping and Improvement

**EDUCATION:** **University of Vermont, Burlington, Vermont**  
Doctor of Philosophy, (Analytical Chemistry), 1992

**United States Army Field Artillery School, 1984**  
Fort Sill, Oklahoma  
Graduated in top 10% of class

**Marine Corps Basic Officer School, 1984**  
Quantico, Virginia

**United States Naval Academy, Annapolis, Maryland**  
Bachelor of Science, 1983 Major: Chemistry (ACS approved curriculum)

**CLIENTS:** **Abbott Vascular, Santa Clara, CA and Temecula, CA**, Medical Device R&D and Manufacturing

**Advent Clinical Research Centers, St. Petersburg, FL**, Clinical Research Organization

**Alturas Analytics, Moscow, ID**, Contract Analytical Laboratory

**Column Engineering, Ontario, CA**, High Performance Liquid Chromatographic Column Manufacturing

**ConMed-Linvatec, Largo, FL**, Medical Device Manufacturing

**Centre Analytical Laboratory, (now Exygen/MPI Research) State College, PA**, Contract Analytical Laboratory

**Florida Inclusion Network, Pinellas County, FL**, Public Education

**LMSi (now a division of Thermo-Fisher), Wilmington, DE**, Contract Instrument Compliance Services Provider

**MDS Pharma Services (now Xcelience), Tampa, FL**, Pharmaceutical Contract Research and Manufacturing Organization

**Merck Pharmaceuticals, West Point, PA**, Pharmaceutical and Vaccine R&D and Manufacturing

**Pinellas County School Board, Largo, FL**, Public Education

**Pfizer Pharmaceuticals, Groton, CT**, Pharmaceutical R&D

**Schering-Plough Pharmaceuticals, Las Piedras, Puerto Rico**, Pharmaceutical Manufacturing

**Supelco (a division of Sigma-Aldrich), State College, PA**, Laboratory Supplies Manufacturer

**VISTAKON®, Jacksonville, FL**, Contract Lens R&D and Manufacturing

**Watson Pharmaceuticals, Humacao, Puerto Rico, and Miami Lakes, FL**, Pharmaceutical Manufacturing

**Wyeth Pharmaceuticals, Pearl River New York and Marietta, PA**, Pharmaceutical and Vaccine R&D and Manufacturing

**Wiley InterScience, John Wiley and Sons, Hoboken, NJ**, Publishers

**RESEARCH  
PUBLICATIONS:**

“Deuterium Nuclear Magnetic Resonance Spectroscopy as a Probe for Reversed-Phase Liquid Chromatographic Bonded Phase Solvation: Methanol and Acetonitrile Mobile Phase Components.” Journal of Chromatography 631, (1993), 23-35, D.M. Bliesner, K.B. Sentell.

“Deuterium Nuclear Magnetic Resonance Spectroscopy as a Probe for Reversed-Phase Liquid Chromatographic Bonded Phase Solvation. 2.

Aqueous Solvation in Methanol and Acetonitrile Binary Mobile Phases." *Analytical Chemistry* 65, (1993) 1819-1826, D.M. Bliesner, K.B. Sentell.

"Graphical Correlation of TLC and HPLC Data in Development of Pharmaceutical compounds." *Journal of Planar Chromatography*, 7, (1994) 197-201, D.M. Bliesner.

"<sup>2</sup>H and <sup>13</sup>C NMR Studies of Reversed-Phase Liquid Chromatographic Stationary Phases: Solvation and Temperature Effects." *Chemically Modified Surfaces*, Royal Society of Chemistry, Cambridge, UK 1994, pp. 190-202. K.B. Sentell, D.M. Bliesner, and S.T. Shearer.

**PRESENTATIONS  
AND PUBLICATIONS:**

**System Peaks for the Study of Interphase Solvation**

1990 Northeastern Regional Meeting of the American Chemical Society, Potsdam, NY, June 27, 1990

**<sup>13</sup>C and <sup>2</sup>H NMR Investigations of Reversed Stationary Phases**

1991 Northeastern Regional Meeting of the American Chemical Society, Amherst, MA, June 24, 1991

Esther Humphrey Symposium, September 13-14, 1991, University of Vermont, Burlington, VT

1992 Pittsburgh Conference and Exposition on Analytical Chemistry and Applied Spectroscopy, New Orleans, LA, March 13, 1992

**Use of TLC in Pharmaceutical Development**

2nd National Symposium on Planar Chromatography, Modern Thin-Layer Chromatography, Research Triangle Park, NC, September 22, 1993, featured speaker

Zeneca Symposium on Separation Science, Zeneca, Inc. Alderly Park, UK, April 25, 1994

**Enhanced Resolution of Parabens and Amines in Oral Solutions**

1998 Pittsburgh Conference, New Orleans, LA. March, 1998

**The Science and Art of Technical Marketing**

Pittsburgh Conference, Orlando, FL, March 2003 and 2005, Chicago, IL. March, 2004

**How to Validate a Chromatographic Method: A Practical Course**

Pittsburgh Conference, Orlando, FL March 2005 and 2006

**How to Establish a GMP Laboratory Audit System**

Pittsburgh Conference, Orlando, FL March 2004

**Introduction to Laboratory CGMPs: A Systems Based Approach**

Pittsburgh Conference, Orlando, FL and Chicago, IL March 2005, 2006 and 2009

**Preparing and Maintaining Laboratory Notebooks and Records**

Pittsburgh Conference, Chicago, IL March 2009

**An Overview of the Enhanced Supported Competitive Employment Program**

SPARC-STAND Invited Speaker Florida Statewide Advocacy Network on Disabilities, Inc., Pinellas Accessing Resources Conference August 2006, September 2007

**Enhancing Supported Competitive Employment by Using CLAASTM Training Tools**

VISIONS conference Jacksonville, FL Conference is sponsored by Florida Special Needs Association (FSNA) and Division of Career Development & Transition (DCDT) February 14-16, 2007

**An Overview of the Enhanced Supported Competitive Employment Program**

Guest lecturer at the University Of Florida Department Of Education for the course EEX 2213 Exceptional People: School and Society, October 30<sup>th</sup> 2007

**Workumentaries: Supporting Student Transition to Work**

Center for Autism and Related Disabilities 15<sup>th</sup> Annual Conference. Invited Speaker January 24-27, 2008

**Introduction to Laboratory Current Good Manufacturing Practices (CGMPs): A Quality Systems Based Approach and Preparing and Maintaining Laboratory Notebooks and Records: An Auditor's Perspective.**

Minnesota Chromatography Forum 28<sup>th</sup> Annual Spring Symposium 15-17, May 2007, invited speaker topics

**Better-Than-Live™ Online Instructional Product for Course Titled Introduction to Laboratory CGMPs: A Quality Systems Based Approach**

BTL™ course for online purchase. May 2008. Created and promoted in partnership with [www.coursecity.com](http://www.coursecity.com)

#### **AUTHORED BOOKS:**

##### **Establishing a CGMP Laboratory Audit System: A Practical Guide**

John Wiley & Sons, Inc. Hoboken, New Jersey, published January, 2006

##### **Validating Chromatographic Methods: A Practical Guide**

John Wiley & Sons, Inc. Hoboken, New Jersey, Published June, 2006. (Best Seller)

##### **Handbook of Analysis and Pharmaceutical Quality**

Chapter Contribution Titled "Systems Based Approach to Laboratory Compliance with the Current Good Manufacturing Practice Regulations (CGMPs)", John Wiley & Sons, Inc. Hoboken, New Jersey, in press, July 2008

#### **GRANTS AND PATENTS:**

Multi-Sensory Instruction System, Patent Pending, application number 10/710461 filed July 13, 2004 with the U.S. Patents and Trademarks office

Delphi Analytical Services, Inc.: Received Employed Worker Training Grant from WorkNet Pinellas, Inc. August 2005 via RFP EWT 05-06-001

Sourced and secured \$240,000 in training funds for clients via Employed Worker Training Grant from WorkNet Pinellas, Inc. during 2005 and 2007

**AWARDS,  
HONORS AND  
SERVICE:**

**Professional:** Invited to do a sabbatical with William H. Pirkle at the University of Illinois at Urbana-Champaign, to investigate chiral HPLC retention mechanisms using NMR March 1992.

Treasurer for Service Academy Business Networking Group of Tampa Bay 1996-1997.

Meritorious Service Letter, Restek Corporation. Awarded for starting Restek Analytical Services Division.

Chair, Central Pennsylvania Section of the American Chemical Society. December 1998- August 1999.

Delphi Analytical Services, Inc. selected and admitted to the Tampa Bay Technology Incubator at the University of South Florida, Tampa Florida, June 2005. The Tampa Bay Technology Incubator exists to support technology research as a catalyst for economic development and advocates the development and construction of facilities for high-technology companies and related support functions. In promoting research with companies and the University of South Florida, the Tampa Bay Technology Incubator seeks to address the needs of local high technology employers in such areas as engineering, biometrics and other technologies.

Member Pinellas County Economic Development Council September 2006 to Present. The Board of County Commissioners and the County Administrator created Pinellas County Economic Development in late 1997. PCED's mission is to retain existing businesses as well as attract new high-quality businesses that pay a living wage. The aim is to improve the business climate within the county by acting as a liaison between public and private sectors while facilitating the availability of a qualified workforce. The mission is accomplished through the initiatives of five sections in the Department: Business Assistance, Business Communication & Marketing, International Business Development, Business Recruitment, and Business Research.

Pinellas Economic Development Council Representative to the Independent Citizens Referendum Oversight Committee (ICROC) May 2007 to present. In the general election of November 2, 2004, voters approved an additional one-half mill ad valorem tax for school district operating expenses for four years

beginning July 1, 2005. ICROC functions as an advisory body to the School Board to advise the School Board on whether the School Board is utilizing the proceeds of the additional one-half mill ad valorem tax for necessary operating expenses including funds to recruit and retain quality teachers; preserve reading programs and music and art classes; and provide up-to-date textbooks and technology.

Baynews 9 Story Extra On Specialist Assignment Topic: "Video Workumentaries." 6 September 2007 (2 minute 30 Second Prime Time News Story).

Runner Up in the Tampa Bay Technology Forum TBTF Innovation of the Year Award, 8 November 2007. Annual Industry Achievement Awards, honoring the Tampa Bay region's best in business and technology. Finalists are selected by a distinguished panel of judges and recognized in front of hundreds at an exciting black-tie awards gala.

Invited to join STAR TEC 20 March 2007. Located on the central west coast of Florida, the STAR (Science Technology and Research) Technology Enterprise Center (STAR TEC) is the Tampa Bay area's first technology and manufacturing business accelerator. Housed within the Young-Rainey Science, Technology, and Research Center, a former Department of Energy facility, STAR TEC supports the growth of early stage manufacturing and technology-based companies, enabling them to migrate their product/service to market more rapidly and effectively.

Invited to be on The Center for Autism and Related Disabilities at the University of South Florida (CARD-USF) Constituency Board July 2008. Position appointed by president of University of South Florida.

Invited to be an adjunct professor of chemistry at Saint Leo University, located in Saint Leo, Florida September 2008.

**Graduate:** University of Vermont Chemistry Department Outstanding Teaching Assistant Award, 1991; Ronald Suiter Student Travel Award, February 1992.

**Professional Military:** Promoted to 1st Lieutenant May 25, 1985. Letter of Appreciation for exemplary performance from the Communications Officer School, Quantico, VA, March 1988; promoted to Captain June 23, 1988.